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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,447	11/30/2001	Nathan Andrew Shapira	UF-260XC1	3440

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/997,447

Applicant(s)
Shapira et al.

Examiner
Phyllis G. Spivack

Art Unit
1614



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 12, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10 and 19-29 is/are pending in the application.
- 4a) Of the above, claim(s) 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 12
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 6, 7, 11 6) ☐ Other:

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A Preliminary Amendment filed January 21, 2003, Paper No. 9, is acknowledged. Claims 1-5 and 11-18 are canceled. New claims 19-29 are presented. Accordingly, claims 6-10 and 19-29 are under consideration.

Applicants' Election filed February 12, 2003, Paper No. 10, is acknowledged. Applicants have elected the species 2,3:4,5-bis-O-(1-methylethylidene)- β -D-fructopyranose sulfamate, topiramate. In the telephone interview of Paper No. 12, Applicants' representative stated an initial examination of this species in a method for promoting wound healing would be acceptable subject matter at this time.

Accordingly, claims 6-10 are now under consideration wherein topiramate is the anti-convulsant agent administered in a method for promoting wound healing. Claims 19-29, as well as other anti-convulsant compounds in a method for promoting wound healing, are presently withdrawn from consideration by the Examiner, 37 C FR 1.142(b), as being directed to non-elected inventions.

Information Disclosure Statements filed June 3, 2002, May 16, 2002, June 24, 2002, November 18, 2002 and June 10, 2003, respectively, Paper Nos. 4-7 and 11, are acknowledged. At the time of the telephone interview, the Examiner offered to obtain U.S. patents when all of the references could not be found from the previous Examiner who had the present case. However, the offer was made without the knowledge that 79 references were part of Paper No. 5. The Examiner regrets the inconvenience associated with resending references but will be unable to

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take the time involved in getting 79 references. All other references have been reviewed to the extent each is in the English language.

Claims 6-10 are rejected under judicially created doctrine as being drawn to an improper Markush group. A proper Markush group must share a substantial structural feature disclosed as being essential. Lack of unity of invention has been found to exist since a common nucleus among the various anti-convulsant agents depicted in Formula I, II, III, IV and V is absent. A prior art reference anticipating the claims under 35 U.S.C. 102 with respect to a species of instant Formula II, for example, would not render the same claims obvious under 35 U.S.C. 103 with respect to another species, such as those of instant Formula V. The members of the instant Markush group possess widely different properties and are not considered functionally equivalent.

Deletion of the non-elected subject matter would resolve the issue.

The claims are examined fully with respect to the elected species only and further to the extent necessary to determine patentability. See MPEP 803.02.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blake et al.,

WO 00/10610.

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Blake teaches the topical administration of topiramate as an anti-convulsant therapeutic agent linked to a non-cytotoxic bioactive moiety. See pages 4-14 and 32. Further, see claims 1, 22 and 23. The claims differ in that multiple conditions and disease states are disclosed. However, one skilled in the art would have been motivated to administer topiramate specifically for promoting wound healing. Such would have been obvious in the absence of evidence to the contrary because the claims show a nexus between wound healing in claim 1 and the administration of the anti-convulsant topiramate in claims 22 and 23. The claims define the invention. Topical administration encompasses the administration of the drug through a dressing, patch, bioadhesive, cosmetic or bandage.

No claim is allowed.

Ellsworth et al., US 2002/0137903, is cited to show further the state of the art with respect to the administration of topiramate in methods for treating delayed wound healing. See pages 3, paragraph [0024] and claim 10, page 15.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number 703-308-4703.

September 7, 2003

A handwritten signature in black ink that reads "Phyllis Spivack". The signature is written in a cursive, flowing style.

**PHYLLIS SPIVACK
PRIMARY EXAMINER**